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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,049	06/20/2007	Jody Stallings	105826-0204-301	8962
13387	7590	11/10/2011	EXAMINER	
Smith & Nephew, Inc (Attention Chief Patent Counsel) 7135 Goodlett Farms Parkway Cordova, TN 38016			PENG, BO JOSEPH	
			ART UNIT	PAPER NUMBER
			3768	
			NOTIFICATION DATE	DELIVERY MODE
			11/10/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/594,049	Applicant(s) STALLINGS ET AL.	
	Examiner BO J. PENG	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,6 and 17-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 6, and 17-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/19/2010, 06/19/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is responsive to the Amendments/Arguments filed on 06/14/2010. Claims 1, 3-5, and 7-16 have been canceled. Claims 2, 6, and 17-19 have been amended. Newly claims 20-46 have been added. Claims 2, 6, and 17-46 are now pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/14/2010 has been entered.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 17-20, 29, and 38 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A claim directed to or including within its scope a human being will not be considered to be patentable subject matter

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under 35 U.S.C. 101 since the grant of a limited, but exclusive property right in a human being is prohibited by the Constitution.

Limitations with positive attachment to the "... body part" includes part of a human being within its scope. With claim 20 as an example, Examiner suggests amending it to "...devices configured to secure the base to be attached to the body part" or the like.

Claim Rejections - 35 USC § 112

4. Claim 21-28, 30-37, and 39-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Examiner is unable to find support for claims that contain "the additional connection aide component having a protrusion connected to eitherwith respect to the second dovetail mating portion. Examiner is unable to find support for claims that contain "the protrusion is a biased member and the receiving ...to receive the biased member." Examiner is unable to find support for claims that contain "the first dovetail mating portion comprises a dovetail pin ... a dovetail tail." Examiner is unable to find claims that contain "the first dovetail mating portion comprises a dovetail tail and ... a dovetail pin." Examiner is unable to find claims that contain "the reference frame and second dovetail ... unitary reference frame."

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 20, 25, 26, 29, 34, 35, 38, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley et al. (Pat. No. 6,226,548, hereinafter Foley '548) in view of Melkent et al. (Pub. No. 2003/0208122, hereinafter Melkent '122).

In re claim 20, Foley '548 teaches a device for use in computer assisted surgery to attach a plurality of indicia capable of being sensed by a computer functionality to a body part involved in surgery, which device comprises: (a) a base (fig. 1a, element 170, col. 7, lines 1-58), comprising; (i) one or more bone attachment devices configured to secure the base to the body part (fig. 1a, element 30, line 35-62); (b) a reference frame

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for holding the plurality of indicia (col. 7, lines 1-9, element 120, 122). Indicia may be secured to the body part in a selectively re-attachable manner (col. 7, lines 10-37).

Foley '548 fails to teach a first dovetail mating portion; and the reference frame having a second dovetail mating portion; wherein the first and second dovetail mating portions are configured to mate in a single orientation and position.

Melkent '122 teaches a first dovetail mating portion (fig. 3, para 0042). Melkent '122 teaches that the reference frame and the base are configured to mate in a single orientation and position (fig. 3 para 0042-0046). Though Melkent '122 fails to explicitly describe a second dovetail mating portion in the reference frame, it would be inherent and/or obvious to have a second dovetail mating portion to match/mate with the first dovetail mating portion to form one set piece (fig. 3).

It would have been *prima facie* obvious to one of ordinary skills in the art at the time of invention to modify the device of Foley '528 to include the dovetail mating portion of Melkent '122 in order to provide better strength and longevity of the connection.

In re claim 29, Foley '548 teaches a system for performing computer assisted surgery on a body part involved in surgery, the system comprising: (a) a plurality of indicia (col. 6, lines 1-20); (b) a computer functionality adapted to sense the position of the plurality of indicia (col. 6, lines 1-20); (c) a base, comprising: (i) one or more bone attachment devices configured to secure the base to the body part (fig. 1a, element 30, line 35-62); (d) a reference frame for holding the plurality of indicia in a reference array

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(col. 7, lines 1-9, element 120, 122), and the indicia may be secured to the body part in a selectively re-attachable manner (col. 7, lines 10-37).

Foley '548 fails to teach a first dovetail mating portion; and the reference frame having a second dovetail mating portion; wherein the first and second dovetail mating portions are configured to mate in a single orientation and position.

Melkent '122 teaches a first dovetail mating portion (fig. 3, para 0042). Melkent '122 teaches that the reference frame and the base are configured to mate in a single orientation and position (fig. 3 para 0042-0046). Though Melkent '122 fails to explicitly describe a second dovetail mating portion in the reference frame, it would be inherent and/or obvious to have a second dovetail mating portion to match/mate with the first dovetail mating portion to form one set piece (fig. 3).

It would have been *prima facie* obvious to one of ordinary skills in the art at the time of invention to modify the device of Foley '528 to include the dovetail mating portion of Melkent '122 in order to provide better strength and longevity of the connection.

In re claim 38, Foley '548 teaches a method of performing computer assisted surgery on a body part involved in surgery, the method comprising: (a) providing a plurality of indicia (col. 6, lines 1-20); (b) providing a computer functionality adapted to sense the position of the plurality of indicia (col. 6, lines 1-20); (c) providing a base, the provided base having one or more bone attachment bone attachment devices configured to secure the base to the body part involved in surgery (fig. 1a, element 30, line 35-62, & abstract), (d) providing a reference frame for holding the plurality of indicia

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in a reference array (col. 7, lines 1-9, element 120, 122), (e) securing the indicia to the body part involved in surgery in a selectively re-attachable manner(col. 7, lines 10-37). (f) performing at least part of the computer assisted surgery based at least in part on information obtained from the computer functionality based on sensing position of the plurality of indicia (col. 6, lines 1-40).

Foley '548 fails to teach a first dovetail mating portion; and the reference frame having a second dovetail mating portion; mating the first and second dovetail portions in a single orientation and position.

Melkent '122 teaches a first dovetail mating portion (fig. 3, para 0042). Melkent '122 teaches that the reference frame and the base are configured to mate in a single orientation and position (fig. 3 para 0042-0046). Though Melkent '122 fails to explicit describe a second dovetail mating portion in the reference frame, it would be inherent and/or obvious to have a second dovetail mating portion to match/mate with the first dovetail mating portion to form one set piece (fig. 3).

It would have been *prima facie* obvious to one of ordinary skills in the art at the time of invention to modify the method of Foley '528 to include the dovetail mating portion of Melkent '122 in order to provide better strength and longevity of the connection.

In re claims 25, 26, 34, 35, 43, and 44, Foley '548 fails to teach a first dovetail mating portion; and the reference frame having a second dovetail mating portion; mating the first and second dovetail portions in a single orientation and position.

Melkent '122 teaches a first dovetail mating portion (fig. 3, para 0042). Melkent '122 teaches that the reference frame and the base are configured to mate in a single orientation and position (fig. 3 para 0042-0046). Though Melkent '122 fails to explicitly describe a second dovetail mating portion in the reference frame, it would be inherent and/or obvious to have a second dovetail mating portion to match/mate with the first dovetail mating portion to form one set piece (fig. 3).

It would have been *prima facie* obvious to one of ordinary skills in the art at the time of invention to modify the device and method of Foley '528 to include the dovetail mating portion of Melkent '122 in order to provide better strength and longevity of the connection.

Furthermore, it would have been obvious matter of design choice to modify the Melkent '122 by having the first dovetail mating portion comprises a dovetail pin and the second dovetail mating portion comprises a dovetail tail, or by having the first dovetail mating portion comprises a dovetail tail and the second dovetail mating portion comprises a dovetail pin. Since the applicant has not disclosed that having different dovetail tail or dovetail pin on each portion solves any stated problem or is for any particular purpose and it appears that the dovetail mating portions of Melkent '122 would perform equally well with each portion regardless which portion is a pin or a tail as long two portions can be mated together.

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8. Claims 2, 6, 21-23, 27, 28, 30-32, 36, 37, 39, 40, 41, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley '548 and Melkent '122 further in view of Thurston (Pat. No. 6,474,901, hereinafter Thurston '901).

In re claims 21, 22, 30, 31, 39, and 40, the combine device of Foley '548 and Melkent '122 fails to teach an additional connection aid component, the additional connection aid component having a protrusion connected to either the first or second dovetail mating portions and further having a receiving portion connected to the other of the first or second dovetail mating portions, the receiving portion configured to receive the protrusion when the first dovetail mating portion is in the single orientation and position with respect to the second dovetail mating portion. And the protrusion is a set screw and the receiving portion is an opening for receiving the set screw.

Thurston '901 teaches the use of screw to strength the dovetail joint between the first dovetail portion and the second dovetail portion through the holes on each dovetail portions (fig. 8, col. 4, line 54 - col. 5, line 4).

It would have been *prima facie* obvious to one of ordinary skills in the art at the time of invention to modify the device of Foley '528 and Melkent '122 to include the screw and protrusion of Thurston '901 to strength the connection.

In re claims 2 and 6, the combine device of Foley '548, Melkent '122, and Thurston teaches claim 21 set forth above. Foley '548 teaches at least one of the indicia includes a reflective surface adapted to be sensed by an infrared sensor device or a transponder that emits energy when interrogated (col. 6, lines 1-20, & col. 8, line 54 - col. 9, line 12).

In re claims 23, 32, and 41, the combine device of Foley '548 and Melkent '122 fails to teach the protrusion is a biased member and the receiving portion is a slot configured to receive the biased member.

Thurston '901 teaches that a biased member and the receiving portion is a slot configured to receive the biased member (fig. 8, col. 4, line 54 - col. 5, line 4).

It would have been *prima facie* obvious to one of ordinary skills in the art at the time of invention to modify the device or method of Foley '528 and Melkent '122 to include the slot and biased member of Thurston '901 to secure the connection.

In re claims 27, 36, and 45, the combine device and method of Foley '548, Melkent '122, and Thurston teaches claim 21 set forth above. Furthermore, Melkent '122 teaches the reference frame and second dovetail mating portion are molded as a single-piece unitary reference frame (fig. 3 para 0042-0046).

In re claims 28, 37, and 46, the combine device and method of Foley '548, Melkent '122, and Thurston teaches claim 21 set forth above. Foley '548 teaches one or more openings in the base for receiving one or more bone screws (col. 6, lines 41-47).

9. Claims 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley '548, Melkent '122, and Thurston '901 further in view of Neubauer et al. (Pub. No. 2002/0068942, hereinafter Neubauer '942).

In re claims 17 and 18, the combine device of Foley '548, Melkent '122, and Thurston '901 fails to teach an adjustable securing mechanism is interposed between the second dovetail mating portion and the indicia, registering and securing mechanism

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and the item, the adjustable securing mechanism including a structure which allows the indicia to be selectively repositioned relative to the body part involved along three rotational degrees of freedom.

Neubauer '942 teaches an adjustable securing mechanism is interposed between the second dovetail mating portion and the indicia, registering and securing mechanism and the item, the adjustable securing mechanism including a structure which allows the indicia to be selectively repositioned relative to the body part involved along three rotational degrees of freedom (para 0034).

It would have been *prima facie* obvious to one of ordinary skills in the art at the time of invention to modify the method and device of Foley '548, Melkent '122, and Thurston '901 to include the adjustable securing mechanism which allows for 3 rotational degrees of freedom of Neubauer '942 in order to allow freely rotate/place indicia in different orientations.

10. Claims 24, 33, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley '548, Melkent '122, and Thurston '901 further in view of Hornik (Pat. No. 2,615,227, hereinafter Hornik '227).

In re claims 24, 33 and 42, the combine device of Foley '548, Melkent '122, and Thurston '901 fails to teach providing an additional magnetic connection aid.

Hornik '227 teaches additional magnetic connection aid (fig. 5, col. 3, lines 55-70).

It would have been *prima facie* obvious to one of ordinary skills in the art at the time of invention to modify the method and device of Foley '548, Melkent '122, and Thurston '901 to include an additional magnetic connection to further strengthen the connection.

Response to Arguments

11. Applicant's arguments with respect to claims 2, 6, and 17-46 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BO J. PENG whose telephone number is (571)270-1792. The examiner can normally be reached on Monday thru Thursday: 8:30am-5:00pm, Alternate Fridays, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/BO J. PENG /
Examiner, Art Unit 3768

/LONG V. LE/
Supervisory Patent Examiner, Art Unit 3768